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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,847	12/15/2000	Ruitang Deng	PC10173BADJ	1841

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EXAMINER
ANGELL, JON E

ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/738,847	DENG ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,45-48,50-52,61 and 70* is/are pending in the application.

4a) Of the above claim(s) *45-48,50 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,51,52 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. This Action is in response to the communication filed on 12/27/02, as Paper No. 11. The amendment has been entered. Claims 37-44, 53-60 65-66 and 71-73 have been cancelled and claims 36, 45-48, 50-52, 61 and 70 have been amended. Claims 36, 45-48, 50-52, 61 and 70 are currently pending in the application and are addressed herein. Claims 45-48, 50 and 70 have been withdrawn from consideration for the reasons of record. Claims 36, 51, 52 and 61 are examined herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36 and 52 remain rejected under 35 U.S.C., second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record. In summary, the claims were rejected because they contained the phrase "significantly reduced infectivity", which renders the claims indefinite. The response to arguments is below.

5. Claim 36 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim is drawn to a method for making an attenuated FIV-141 virus comprising **mutating an ENV gene**. (Emphasis added). However, the claim is unclear because it refers to mutating "an ENV gene", however it only appears that one ENV gene is presented in the claim, that being the FIV-151 ENV gene. It is unclear is there is another ENV gene that could be mutated and result in the attenuated FIV-141 virus. Therefore the claim is indefinite. Amending the claim to recite (for example) a method for making an attenuated FIV-141 virus... wherein said method comprises mutating the FIV-141 ENV gene, would obviate this rejection. It is noted, however, that the suggested claim does not overcome the 112, first paragraph rejection (enablement) set forth below.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 36, 51, 52, and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass ENV mutations for which there is no written description in the specification. For instance, the claims encompass any mutation of the ENV gene which results in an attenuated FIV-141 virus (claim 31) or nucleic acid suitable for use in a vaccine for FIV-141 virus infection (claim 51). Therefore the claims encompass any substitution, addition or deletion of the ENV gene. However, the specification only discloses a single ENV mutation, that is a deletion of nucleotides 6577-8679 of the FIV-141 ENV gene.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (See MPEP 2100-164)

Here, there is no disclosure of any other ENV mutation other than the deletion mentioned above. Furthermore, there is no disclosure indicating which other mutations would result in the desired outcome. There is not identification of the critical and non-critical nucleotides within the nucleotides 6577-8679. Therefore on of skill in the art would not know which mutations other than deletion of the FIV-141 ENV gene comprising a deletion of nucleotides 6577-8679 would result in the desired outcome without performing additional experimentation. (Note, amending the claims as suggested below would obviate this rejection).

8. Claims 36, 51, 52 and 61 are also rejected under 35 U.S.C. 112, first paragraph in view of the written description rejection above, because the specification, while being enabling for:

A method for making an attenuated FIV-141 virus that replicates upon entry into a host cell but which exhibits significantly reduced infectivity to feline T lymphocytes relative to wild type FIV-141 virus, wherein said method comprises making a mutation in the FIV-141 ENV gene, wherein said mutation comprises a deletion of nucleotides 6577-8679 of the FIV-141 ENV gene;

and,

A method of producing a nucleic acid molecule suitable for use in a vaccine for FIV-141 virus infection, wherein said method comprises:

a) reverse transcribing the FIV-141 viral genomic RNA;

b) cloning the reverse transcript of step (a);

c) making a mutation in the FIV-141 ENV gene of the cloned nucleic acid of step (b), wherein said mutation comprises a deletion of nucleotides 6577-8679 of the FIV-141 ENV gene;

d) cloning the mutated nucleic acid of step (c);

does not reasonably provide enablement for a method of making an attenuated FIV-141 virus or a method for producing a nucleic acid molecule suitable for use in a vaccine for FIV-141 virus infection wherein said methods comprise making any possible mutation of the FIV-141 ENV gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As mentioned above, the claims encompass mutations for which there is no written description provided in the specification. Without a clear indication of the mutations encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

9. Claims 31, 51, 52 and 61 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

10. The claims refer to a specific (FIV-141) which the specification indicates has been deposited; however, the deposit rules are not met. MPEP 2402 states "Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112." Specifically, the specification fails to provide the correct (new) address of the depository, a taxonomic description of the deposit, a statement that all restrictions will be lifted on accessing the deposit upon patent issuance, and there is no statement regarding the term of the deposit. Without access to the deposited material one of skill in the art would not be able to make and use the claimed invention without an undue amount of additional experimentation in order to isolate the specific FIV-141 strain.

Response to Arguments

Claims 36 and 52 remain under 35 USC 112, second paragraph for the reason of record.

Applicant's arguments filed 12/27/02 have been fully considered but they are not persuasive. Applicants argue that the claims have been amended to recite "significantly reduced infectivity to feline T lymphocytes relative to wild type FIV-141..." thus rendering the rejection moot in view of the amendment.

This is not considered persuasive, because the term "significantly reduce" still appears in the claims, but is not defined in the specification or the claims. It is pointed out the significantly reduced is a relative term. Without a clear definition in the specification or the claims it is unclear what would be "significant reduction", even when compared to the wild-type FIV-141. The metes and bounds of the relative term "significant" has not been defined, therefore one of skill in the art would not know how much reduction would be insignificant and how mush would be significant. For instance one of skill in the art would not know if 5% or 75% reduced compared to wild type is significant or insignificant. Therefore the claims are indefinite.

With respect to rejection of claims under 35 USC 112, first paragraph, applicants argue that the claims have been amended to specify the FIV-141 virus and to specify a mutation in the ENV gene.

Applicant's arguments filed 12/27/02 have been fully considered but they are not persuasive. Although the claims have been amended, the claims still encompass mutations for which there is no written description provided in the specification for the reasons set forth above.

With respect to the rejection of claims under 35 USC 112 because of an improper deposit. It is acknowledged that the only previous claims encompassing the FIV-141 virus has been cancelled, however, all of the pending claims are now drawn to the FIV-141 virus. Therefore the

rejection of claims 56-60 are rendered moot because the claims have been canceled, the rejection of claims 31, 51, 52 and 61 for the reasons set forth above (regarding deposit rules) are appropriate and necessitated by amendment.

The rejection of claims under 35 USC 102 are either withdrawn because of the amendment (limiting the claims to FIV-141) or moot because of the cancellation of claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
March 10, 2003